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Attorneys for Plaintiff
ELEKTA LIMITED and ELEKTA, INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

ELEKTA LIMITED and ELEKTA, INC.,

Plaintiffs,

v.

ZAP SURGICAL SYSTEMS, INC.,

Defendant.

Case No.

**COMPLAINT FOR PATENT
INFRINGEMENT**

Plaintiffs Elekta Limited and Elekta, Inc. ("Plaintiffs"), by and through their undersigned counsel, file this complaint against ZAP Surgical Systems, Inc. ("Defendant" or "ZAP"), and allege as follows:

NATURE OF THE ACTION

1. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*, as the result of ZAP's direct and indirect infringement of U.S. Patent No. 7,295,648 (the "'648 Patent" or "Asserted Patent") by the sale, offer for sale, manufacture, use, exportation from and/or importation into the United States of its ZAP-X® Gyroscopic Radiosurgery™ Platform ("ZAP-X").

2. By virtue of this action, Elekta Limited and Elekta, Inc., seek a preliminary and/or permanent injunction that prohibits ZAP from exporting, importing, making, using, selling and

1 offering to sell the ZAP-X from or into or in the U.S., and further prohibits ZAP from advertising,
2 showing, promoting, supporting or offering training in the use of ZAP-X in the U.S., as well as
3 monetary damages.

4 THE PARTIES

5 3. The Elekta group of companies ("Elekta Group") is a pioneering family of
6 biomedical-engineering companies founded in 1972 by Professor Lars Leksell, the inventor of
7 radiosurgery and developer of the Leksell Gamma Knife®. The Elekta Group develops sophisticated,
8 state-of-the-art tools and treatment planning systems for radiation therapy, radiosurgery and
9 brachytherapy, as well as workflow enhancing software systems across the spectrum of cancer care.
10 Elekta Group solutions in oncology and neurosurgery are used in over 6,000 hospitals worldwide.

11 4. Elekta Limited is a foreign entity organized and existing under the laws of the
12 United Kingdom, with its principal place of business at Linac House, Fleming Way, RH10 9RR
13 Crawley, United Kingdom.

14 5. Elekta, Inc. is a corporation organized and existing under the laws of the State of
15 Georgia, with its principal place of business at 400 Perimeter Center Terrace, Suite 50, Atlanta,
16 Georgia 30346.

17 6. Upon information and belief, Defendant ZAP Surgical Systems, Inc., is an early
18 stage surgical device company incorporated in the State of Delaware with its principal place of
19 business in California at 590 Taylor Way, San Carlos, California, and its principal executive
20 office at 15F No 207-1 Sec 3 Beixin Rd Xindian Dist, New Taipei City, 231 Taiwan.

21 7. Upon information and belief, ZAP's founder and current CEO is John R. Adler,
22 currently residing in Stanford, California.

23 JURISDICTION AND VENUE

24 8. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C.
25 §§ 1331 and 1338(a).

26 9. Upon information and belief, this Court has personal jurisdiction over ZAP
27 because its principal place of business is located in this District and because ZAP has committed
28

1 acts of patent infringement and/or contributed to or induced acts of patent infringement by others
2 in the State of California and in this District. As such, ZAP has established sufficient minimum
3 contacts with this District such that it should reasonably and fairly anticipate being called into
4 court in this District, and Zap has purposefully directed activities at residents of this state and this
5 District.

6 10. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b)
7 because ZAP has a regular and established place of business in this District and has committed
8 acts of infringement in this District.

9 BACKGROUND TO THE ACTION

10 11. For almost five decades, the Elekta Group and its founders have led the fight against
11 cancer as pioneers in the development of precision radiation medicine and individually tailored
12 radiotherapy treatment. The Elekta Group's focus today is the same as it was 50 years ago—targeting
13 the tumor while protecting the patient.

14 12. The Elekta Group's founder, Professor Lars Leksell, was the developer of the advanced
15 radiosurgical platform that bears his name: the Leksell Gamma Knife®. The Elekta Group's Leksell
16 Gamma Knife® product continues to be the gold standard for stereotactic radiosurgery and the
17 treatment of neurological disorders. For example, in 2015, the Elekta Group offered the first online
18 adaptive radiosurgery system with the Leksell Gamma Knife Icon™.

19 13. In addition to developing the Gamma Knife®, the Elekta Group has innovated in
20 other radiotherapy technologies. In 2003, Elekta Limited was the first to integrate cone beam
21 computed tomography (CBCT) imaging with radiotherapy treatment. In 2012, Elekta Limited
22 introduced the Agility™ highresolution beam shaping solution. In 2018, Elekta Limited
23 introduced the first high-field magnetic resonance radiation therapy product for personalized
24 precision radiation therapy: the Elekta Unity.

25 14. The Elekta Group's leadership position in precision radiation medicine is the result
26 of its substantial investment in cutting-edge research and its dedicated focus on leveraging the
27 intelligence of information-guided care.
28

15. As the result of its innovative research, the Elekta Group has obtained hundreds of patents worldwide on its novel hardware and software solutions that push the boundaries of precision radiation medicine for treating the most complicated forms of cancer.

THE PATENTED TECHNOLOGY

16. The '648 Patent is entitled "Method and Apparatus for Treatment by Ionizing Radiation" and identifies Kevin John Brown as the inventor.

17. The '648 Patent describes a new design for a very precise radiation therapy machine having a radiation source mounted in such a way that it can rotate around one axis and then rotate around an intersecting axis to deliver therapeutic radiation from multiple different angles around a patient.

18. The application for the '648 Patent was filed on October 21, 2004, claiming priority to Applications Nos. 324676.6 and 325698.9, filed in Great Britain on October 23, 2003 and November 4, 2003, respectively, and the '648 Patent issued on November 13, 2007, after being duly examined by the United States Patent and Trademark Office.

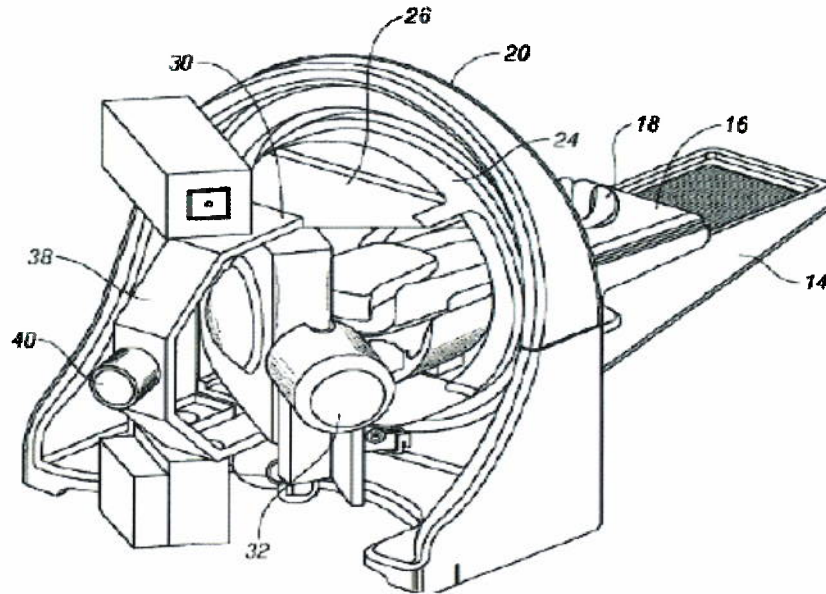
19. The '648 Patent is one of multiple patents granted globally claiming priority to Great Britain Applications Nos. 324676.6 and 325698.9.

20. A true and correct copy of the '648 Patent is attached as **Exhibit A**.

21. The '648 Patent describes a radiation therapy device for neurosurgery in the Abstract as follows:

The device comprises a rotateable support, on which is provided a mount extending from the support out of the plane of the circle, and a radiation source attached to the mount via a pivot, the pivot having an axis which passes through the axis of rotation of the support, the radiation source being aligned so as to produce a beam which passes through the coincidence of the rotation axis and the pivot. ... A particularly preferred orientation is one in which the radiation source is spaced from the rotateable support, to allow it to pivot without fouling the latter. ... Another way of expressing this preference is to state that the pivot axis is located out of the plane of the rotateable support. ... It is preferred that the radiation source is a linear accelerator. The output of the radiation source is preferably collimated to conform to the shape of the area to be treated.

22. Figure 7 of the '648 Patent shows one embodiment of the invention claimed in the '648 Patent:



23. As explained in the '648 Patent, Figure 7 shows a linear accelerator or "LINAC" 32 inside an enclosure. The LINAC 32 is mounted on pivotal mounting points 30, such that it can move to the right or left along an imaginary ring (not shown) centered on the line through the mounting points 30. This structure is in turn mounted on a second rotateable ring 24, which can rotate the mounting structure with the LINAC 32 around the patient 18 lying on the table 14.

24. Claim 1 of the '648 Patent reads as follows:

A device for treating a patient with ionising radiation comprising:
 a ring-shaped support, on which is provided a mount, a radiation source attached to the mount;
 the support being rotateable about an axis coincident with the centre of the ring;
 the source being attached to the mount via a rotateable union having an [sic] axis of rotation axis which is non-parallel to the support axis;
 wherein the rotation axis of the mount passes through the support axis of the support and the radiation source is collimated so as to produce a beam which passes through the co-incidence of the rotation and support axes.

25. Claim 18 of the '648 Patent reads as follows:

A method of treating a patient with a source that emits a beam of radiation in a direction emanating therefrom, comprising the steps of:

- i. providing a ring-shaped support for the source, the support permitting rotation about two axes each offset from the source, with both axes and the beam direction all being co-incident at a single isocentre;
- ii. positioning the patient such that a diseased area of tissue is located at the isocentre;
- iii. activating the source;
- iv. causing rotation of the source about the two axes to achieve a greater dosage at the isocentre than around the isocentre, wherein the rotation takes place via a rotateable union of the source to the support.

26. Elekta Limited is the owner under applicable law and by assignment of all right, title, and interest in the '648 Patent, including the rights to sue, recover damages and obtain equitable relief for the patent's infringement. Elekta, Inc. is the licensee of the '648 Patent for the United States.

THE ACCUSED ZAP-X TECHNOLOGY

27. Upon information and belief, ZAP imports into and/or makes, uses, sells, and offers to sell in the U.S. the ZAP-X® Gyroscopic Radiosurgery™ Platform ("ZAP-X") and/or equivalent products.

28. ZAP says that its ZAP-X is "what's next in non-invasive cancer treatment," being "[d]esigned exclusively for the streamlined treatment of brain tumors and conditions of the head and neck" with technology that "provides diverse non-coplanar radiation dose delivery while eliminating the need for live radioactive sources." *See zapsurgical.com*.

29. ZAP has advertised and displayed its ZAP-X Platform in the United States, including at the conference of the Radiosurgery Society in San Diego on March 21-23, 2019.

30. ZAP has also advertised and displayed its ZAP-X Platform at the conference of the American Association of Neurological Surgeons (AANS) held April 13-17, 2019, in San Diego, California, as indicated by its posting on LinkedIn, shown below.

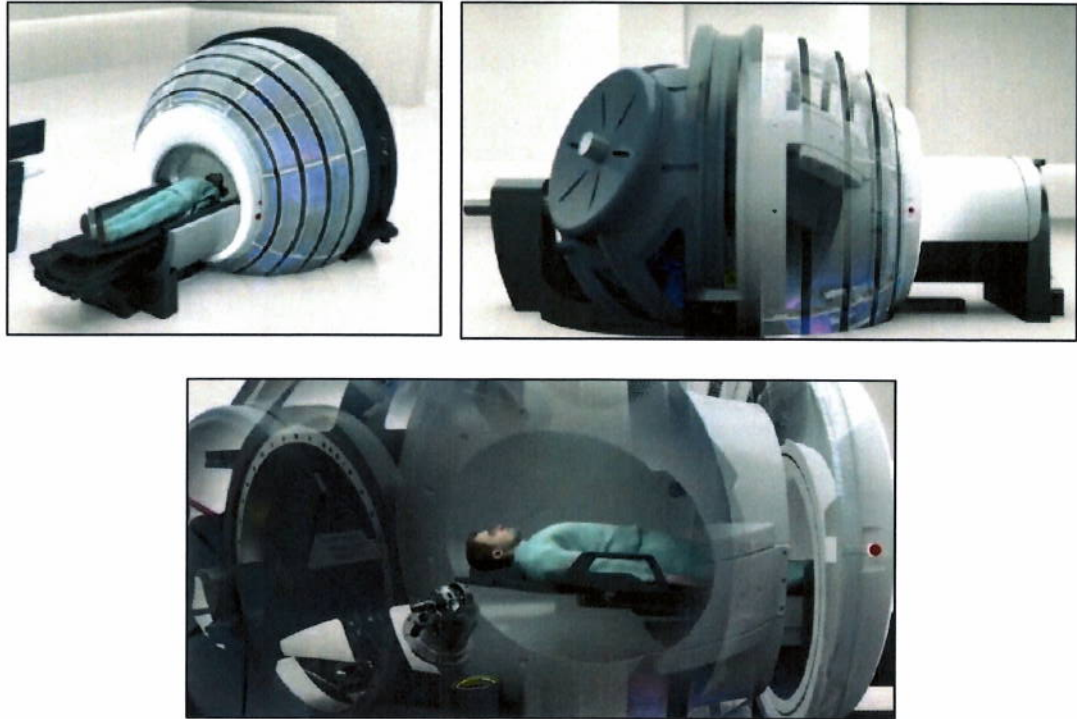


31. The U.S. Food and Drug Administration (“FDA”) described the ZAP-X in its 510(k) Summary dated February 24, 2019, as follows:

The modified Zap-X Radiosurgery System (‘Zap-X System’) is a computer-controlled system for performing non-invasive stereotactic radiosurgery that is self-shielded for ionizing radiation. A gantry-mounted linear accelerator provides the modified Zap-X System with a source of therapeutic radiation and a kV imaging system is used to accurately locate the treatment target.

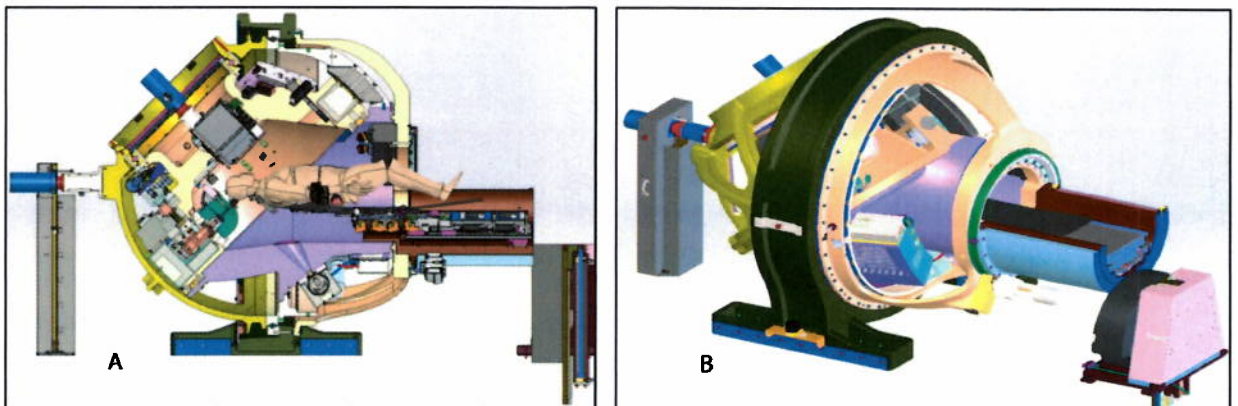
32. The FDA defined the Indications for Use of the ZAP-X in its 510(k) Summary dated February 24, 2019, as follows: “The modified Zap-X Radiosurgery System is intended to provide treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for tumors, lesions and conditions in the brain, head and neck when radiation treatment is indicated.”

33. The images below, from a video available at the time of filing of this Complaint on the internet at https://www.youtube.com/watch?time_continue=9&v=zCpI6p8X9Jg and/or <https://zapsurgical.com/>, show the design of the ZAP-X® Gyroscopic Radiosurgery™ Platform.



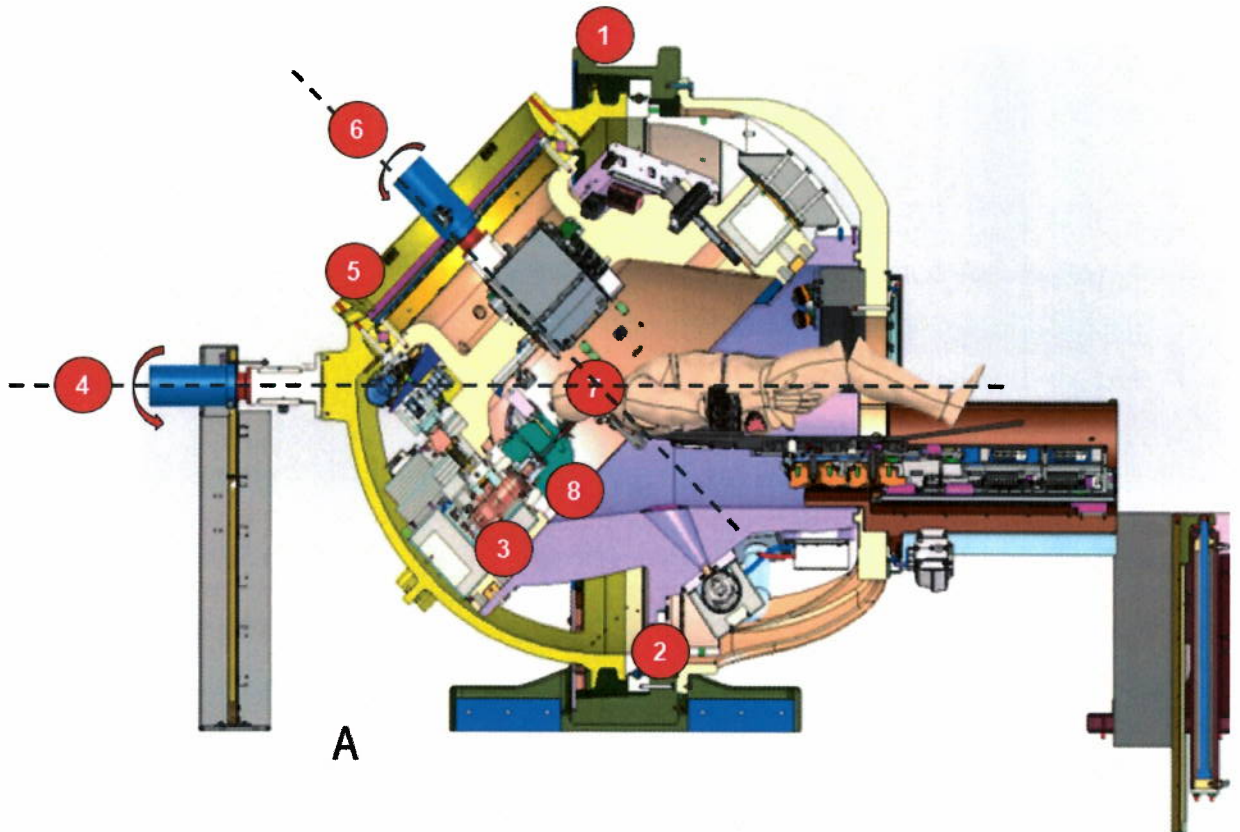
34. The ZAP-X uses a LINAC to deliver radiation therapy, and the radiation head of the LINAC is mounted in such a way that it can rotate around one axis, and then rotate around an intersecting axis, to deliver therapeutic radiation from multiple different angles around a patient.

35. The diagrams below, available at the time of filing of this Complaint on the internet at www.cureus.com/articles/9924-self-shielding-analysis-of-the-zap-x-system, show the components and design of a ZAP-X.



36. The ZAP-X is a device for treating a patient with ionizing radiation as recited in claim 1 of the '648 Patent.

37. As indicated in the diagram below, ZAP-X has a ring-shaped support (1), on which is provided a mount (2), with a radiation source (3) attached to the mount. The support is rotateable about an axis (4) coincident with the center of the ring (1), as also shown in the video available at zapsurgical.com/#zap-x. The source is attached to the mount via a rotateable union (5) having an axis of rotation (6) which is non-parallel to the support axis. The rotation axis of the mount passes through (7) the support axis of the support, as also shown in the video available at zapsurgical.com/#zap-x. In addition, the radiation source is collimated (8) to produce a beam which passes through the co-incidence of the rotation and support axes.



38. According to a news release dated February 6, 2019, and available on the internet at the time of filing of this complaint, a ZAP-X provided by ZAP has been used in clinical treatment of a patient at Barrow Brain and Spine, a partner of Barrow Neurological Institute in Phoenix, Arizona. See www.barrowbrainandspine.com/blog/newsroom/barrow-brain-spine-zap-x-non-invasive-radiosurgery/.

39. As indicated in the diagram above and shown in a video available at the time of filing of this Complaint on the internet at *zapsurgical.com/* and/or *https://www.youtube.com/watch?time_continue=9&v=zCpI6p8X9Jg*, ZAP-X provides a method of treating a patient with a source (3) that emits a beam of radiation in a direction emanating therefrom. There is a ring-shaped support (1) for the source, the support permitting rotation about two axes, (4) and (6), each offset from the source, with both axes and the beam direction all being co-incident at a single isocentre (7). The patient is positioned such that a diseased area of tissue is located at the isocentre (7). The source is activated. The source is rotated, via a rotateable union of the source to the support, about the two axes to achieve a greater dosage at the isocentre than around the isocentre.

ZAP'S KNOWLEDGE OF THE '648 PATENT

40. ZAP has known about the '648 Patent since at least April 6, 2015.

41. On April 6, 2015, an Information Disclosure Statement (IDS) was submitted to the U.S. Patent and Trademark Office (USPTO) as part of Application 13/310,582, which names John R. Adler as an inventor. The IDS identified the '648 Patent.

42. On May 18, 2016, another IDS was submitted to the USTPO, as part of Application 14/017,992, which also names John R. Adler as an inventor. That IDS also identified the '648 Patent.

43. The disclosure of the '648 Patent to the USPTO during the prosecution of these patent applications indicates that ZAP's CEO, and thus ZAP, had actual knowledge of the '648 Patent at least as of April 6, 2015.

44. Despite its actual knowledge of the '648 Patent, ZAP continues its infringement.

COUNT I

(Direct Infringement of U.S. Patent No. 7,295,648)

45. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs of this Complaint as if fully set forth herein.

the use of the ZAP-X[®] Gyroscopic Radiosurgery[™] Platform and equivalent products (the “Accused Products”) in the United States without license or authority.

53. ZAP has actively encouraged infringement, knowing that the acts it has induced constituted patent infringement, and its encouraging acts have resulted in direct patent infringement.

54. Because use of the ZAP-X meets each limitation of at least claims 1 and 18 of the ’648 Patent in the manner shown above, and because ZAP has had actual knowledge of the ’648 Patent as of at least April 6, 2015, ZAP’s inducement of infringement has been willful.

55. ZAP’s inducement of infringement of the ’648 Patent has damaged Plaintiffs, by violating Plaintiffs’ right to exclude others from importing into and making, using, selling and offering to sell covered apparatuses and/or methods in the U.S.

56. Upon information and belief, the ZAP-X product is being marketed as an alternative to the Elekta Group’s Leksell Gamma Knife[®] products, including the Icon[™] and Perfexion[™], thereby potentially reducing sales of the Leksell Gamma Knife[®] products.

57. For at least the reasons set forth in the preceding paragraph, ZAP’s continuing inducement of infringement of the ’648 Patent irreparably harms Plaintiffs, and Plaintiffs will continue to suffer irreparable harm absent entry of a permanent injunction enjoining ZAP and all others acting with it from infringing the ’648 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in favor of Plaintiffs and against ZAP as follows:

- A. Finding that ZAP is and has been infringing the ’648 Patent;
- B. Issuing a permanent injunction that prohibits ZAP and its affiliates, employees, agents, officers, directors, attorneys, successors, and assigns, and all those acting on behalf of or in active concert or participation with any of them, from exporting, importing, making, using, selling and offering to sell the ZAP-X from, or into or in the U.S.; advertising, showing, promoting, supporting or offering training in the use of ZAP-X in the U.S.; and otherwise directly

infringing or inducing infringement of the '648 Patent;

C. Requiring that ZAP render a full and complete accounting to Plaintiffs for ZAP's profits, gains, advantages or the value of business opportunities received from its acts of infringement;

D. Requiring that ZAP pay Plaintiffs damages sufficient to compensate Plaintiffs for ZAP's infringement of the '648 Patent, including lost profits suffered by Plaintiffs as a result of ZAP's infringement and in an amount not less than a reasonably royalty;

E. Enhancing by three-fold the damages that ZAP must pay Plaintiffs pursuant to 35 U.S.C. § 284;

F. Finding the case exceptional under 35 U.S.C. § 285 and requiring that ZAP pay to Plaintiffs all of its attorneys' fees and costs and expenses in this action;

G. Awarding Plaintiffs prejudgment interest, post-judgment interest, and costs; and

H. Such other and further relief as the Court may deem appropriate.

JURY DEMAND

Plaintiffs respectfully demand a trial by jury on all issues raised by this Complaint that are properly triable by a jury.

Dated: April 26, 2019

Squire Patton Boggs (US) LLP

By: /s/ Tamara Fraizer
Tamara Fraizer

Attorneys for Plaintiffs
Elekta Limited and Elekta, Inc.